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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|--|------------------------------------|----------------------|---------------------|------------------|--|
| 10/533,764 | 05/04/2005 | William Brown | 100884-1P US | 6329 | |
| 22466 ASTRA ZENE | 7590 01/10/200 ECA PHARMACEUTIO | EXAMINER | | | |
| GLOBAL INTELLECTUAL PROPERTY 1800 CONCORD PIKE WILMINGTON, DE 19850-5437 | | | MOORE, SUSANNA | | |
| | | | ART UNIT | PAPER NUMBER | |
| | • | | 1624 | | |
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| | | | MAIL DATE | DELIVERY MODE | |
| | | | 01/10/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief

| Applicant(s) | |
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| BROWN ET AL. | |
| Art Unit | |
| 1624 | |
| | BROWN ET AL. Art Unit |

| | Susanna Moore | 1624 | | | | | |
|--|---|---|--|--|--|--|--|
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | | | |
| THE REPLY FILED <u>27 December 2006</u> FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. | | | | | | | |
| The reply was filed after a final rejection, but prior to or on this application, applicant must timely file one of the follow places the application in condition for allowance; (2) a No a Request for Continued Examination (RCE) in compliance time periods: The period for reply expires 3 months from the mailing date b) The period for reply expires on: (1) the mailing date of this A no event, however, will the statutory period for reply expire lateral | ving replies: (1) an amendment, affitice of Appeal (with appeal fee) in one with 37 CFR 1.114. The reply mut of the final rejection. dvisory Action, or (2) the date set forth | idavit, or other evider compliance with 37 C ust be filed within one in the final rejection, wh | ice, which FR 41.31; or (3) of the following ichever is later. In | | | | |
| Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). | | | | | | | |
| Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL | | | | | | | |
| 2. The Notice of Appeal was filed on A brief in comp filing the Notice of Appeal (37 CFR 41.37(a)), or any external Notice of Appeal has been filed, any reply must be filed AMENDMENTS | nsion thereof (37 CFR 41.37(e)), to | avoid dismissal of th | ns of the date of e appeal. Since | | | | |
| 3. The proposed amendment(s) filed after a final rejection, | but prior to the date of filing a brief, | , will <u>not</u> be entered b | ecause | | | | |
| (a) ☐ They raise new issues that would require further composition (b) ☐ They raise the issue of new matter (see NOTE belomotion) (c) ☐ They are not deemed to place the application in bet appeal; and/or (d) ☐ They present additional claims without canceling a decirion. | nsideration and/or search (see NO w); ter form for appeal by materially re | TE below); ducing or simplifying | | | | | |
| NOTE: (See 37 CFR 1.116 and 41.33(a)). | | | | | | | |
| 4. The amendments are not in compliance with 37 CFR 1.13 5. Applicant's reply has overcome the following rejection(s) 6. Newly proposed or amended claim(s) would be all non-allowable claim(s). | : | | : G | | | | |
| 7. For purposes of appeal, the proposed amendment(s): a) how the new or amended claims would be rejected is proposed. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: 1-10,13,14 and 17-21. Claim(s) objected to: Claim(s) rejected: 16. Claim(s) withdrawn from consideration: AFFIDAVIT OR OTHER EVIDENCE | | II be entered and an e | explanation of | | | | |
| 8. The affidavit or other evidence filed after a final action, but because applicant failed to provide a showing of good answas not earlier presented. See 37 CFR 1.116(e). | | | | | | | |
| 9. The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to of showing a good and sufficient reasons why it is necessar | vercome <u>all</u> rejections under appe y and was not earlier presented. S | al and/or appellant fa ee 37 CFR 41.33(d)(| ils to provide a 1). | | | | |
| 10. ☐ The affidavit or other evidence is entered. An explanatio REQUEST FOR RECONSIDERATION/OTHER | n of the status of the claims after e | ntry is below or attacl | ned. | | | | |
| 11. The request for reconsideration has been considered bu See memo. | t does NOT place the application in | n condition for allowa | nce because: | | | | |
| 12. Note the attached Information Disclosure Statement(s).13. Other: | (PTO/SB/08) Paper No(s) | | | | | | |
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DETAILED ACTION

Applicant has amended claim 7 to include "I" below the formula in said claim for clarification purposes only. Thus, the amendments will be entered.

Applicant's arguments regarding the enablement rejection of claim 16 have been fully considered but they are not persuasive. On pages 14-15, Applicant repeatedly sites passages from the Specification that provide support for delta opioid receptor agonist activity. This is not the issue at hand. Claim 16 is drawn to a method of treating anxiety. A definitive correlation between anxiety and a delta opioid receptor agonist is the connection that needs to be made.

Applicants state at the bottom of page 16 and the top of page 17, "Applicants, however, are perplexed by this assertion because as Applicants have already pointed out hereinabovethe application as-filed clearly stated that the 79 example and at least some of the 8 intermediate compounds disclosed therein were found to be active toward human delta opioid receptors via the assays and testing protocols set forth therein. Moreover, the specification further states that "[f]or the anxiety and anxiety-like indications, efficacy has been established in the geller-seifter conflict test in the rat."" Applicant has only established enablement for the inhibition of the delta opioid receptor, not anxiety. Applicant has not provided any working examples or data to support the statement. Was one compound tested or a representative sample of the genus tested? The geller-seifter assay is an acceptable assay known in the literature to test for anxiety in vivo but Applicants lack actual data. The Examiner cannot determine if the tested compound even falls within the claimed genus. No data is present in the Specification for treatment of anxiety in general, either directly or in form of animal models.

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Such testing, if verified, aould overcome the rejection, but this bare sentence is not sufficient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susanna Moore whose telephone number is (571) 272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Mark L. Berch
Primary examiner
Art Unit 1624
Technology Center 1600